EMA/532503/2021

European Medicines Agency decision

P/0444/2021

of 22 November 2021

on the acceptance of a modification of an agreed paediatric investigation plan for single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Spikevax), (EMEA-002893-PIP01-20-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0481/2020 issued on 30 November 2020,

Having regard to the application submitted by MODERNA BIOTECH SPAIN, S.L. on 21 May 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 September 2021, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006, an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Spikevax), dispersion for injection, intramuscular use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to MODERNA BIOTECH SPAIN, 30 S.L. Calle Monte Esquinza, 28010 – Madrid, Spain.

EMA/PDCO/598504/2021
Amsterdam, 12 November 2021

Final opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-002893-PIP01-20-M01

Scope of the application

Active substance(s):

Single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2

Invented name:

Spikevax

Condition(s):

Prevention of coronavirus disease 2019 (COVID-19)

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Dispersion for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

MODERNA BIOTECH SPAIN, S.L.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, MODERNA BIOTECH SPAIN, S.L. submitted to the European Medicines Agency on 21 May 2021 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0481/2020 issued on 30 November 2020.

The application for modification proposed changes to the agreed paediatric investigation plan.

An Opinion was adopted by the Paediatric Committee on 10 September 2021 for the above mentioned product. MODERNA BIOTECH SPAIN, S.L. received the Paediatric Committee Opinion on 20 September 2021.

On 19 October 2021 MODERNA BIOTECH SPAIN, S.L. submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 20 October 2021.

Scope of the modification

Some measures of the Paediatric Investigation Plan have been modified.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

1.1. to revise its opinion and

- to agree to the changes regarding the measures in the scope set out in the Annex I of this opinion.

The Norwegian Paediatric Committee members agrees with the above-mentioned recommendation of the Paediatric Committee.

The measures and timelines of the agreed paediatric investigation plan are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Prevention of coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Prevention of coronavirus disease 2019 (COVID-19)

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Dispersion for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	3	**Study 1 (P203)** Randomized, observer-blind, placebo-controlled, study to evaluate safety, reactogenicity, and immunogenicity of single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (CX-024414) in adolescents from 12 to less than 18 years of age for prevention of COVID-19. **Study 2 (P204)** Randomized, observer-blind, placebo-controlled, study to evaluate dose finding (part 1), and safety, reactogenicity, and immunogenicity (part 2) of CX-024414 in children from birth to less than 12 years of age for prevention of COVID-19. **Study 3** Open label, uncontrolled, safety and immunogenicity study of CX-024414 in immunocompromised children and adolescents from birth to less than 18 years of age for prevention of COVID-19.

Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long-term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of COVID-19

Authorised indication(s):

- Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.

Authorised pharmaceutical form(s):

Dispersion for injection

Authorised route(s) of administration:

Intramuscular use